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In re Application of:

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JAIN et al.

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Serial No.: 09/337,675

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Group Art Unit: 1615

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Filed: June 22, 1999

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Examiner: A. Pulliam

For: CONTROLLED RELEASE NANO-
PARTICULATE COMPOSITIONS

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Commissioner for Patents
Washington, D.C. 20231

5-23-02

Sir:

PRELIMINARY AMENDMENT

Prior to examination on the merits, please amend this application as follows.

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~~37. (New) The composition of claim 1, wherein the surface stabilizer is selected from the group consisting of gelatin, casein, lecithin, dextran, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, poloxamers, poloxamines, Tetronic 1508®, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a mixture of sucrose stearate and sucrose distearate, p-isobutylphenoxy poly-(glycidol), Crodestas SL-40®, SA9OHCO, decanoyl-N-methylglucamide, n-decyl β-D-~~

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glucopyranoside, n-decyl β -D-maltopyranoside, n-dodecyl β -D-glucopyranoside, n-dodecyl β -D-maltoside, heptanoyl-N-methylglucamide, n-heptyl- β -D-glucopyranoside, n-heptyl β -D-thioglucoside, n-hexyl β -D-glucopyranoside, nonanoyl-N-methylglucamide, n-noyl β -D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl- β -D-glucopyranoside, and octyl β -D-thioglucopyranoside.

38. (New) The composition of claim 1, wherein the drug is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antiasthma agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antitussives, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, antipyretics, immunosuppressants, immunostimulants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, bronchodilators, cardiac inotropic agents, chemotherapeutics, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, proteins, polypeptides, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, hormones, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vaccines, vasodilators, and xanthines.

39. (New) The composition of claim 1, wherein the drug is selected from the group consisting of alprazolam, amiodarone, amlodipine, astemizole, atenolol, azathioprine, azelatine, beclomethasone, budesonide, buprenorphine, butalbital, carbamazepine, carbidopa, cefotaxime, cephalexin, cholestyramine, ciprofloxacin, cisapride, cisplatin, clarithromycin, clonazepam, clozapine, cyclosporin, diazepam, diclofenac sodium, digoxin, dipyridamole, divalproex, dobutamine, doxazosin, enalapril, estradiol, etodolac, etoposide, famotidine, felodipine, fentanyl citrate, fexofenadine, finasteride, fluconazole, flunisolide, flurbiprofen, fluvoxamine, furosemide, glipizide,

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gliburide, ibuprofen, isosorbide dinitrate, isotretinoin, isradipine, itraconazole, ketoconazole, ketoprofen, lamotrigine, lansoprazole, loperamide, loratadine, lorazepam, lovastatin, medroxyprogesterone, mefenamic acid, methylprednisolone, midazolam, mometasone, nabumetone, naproxen, nicergoline, nifedipine, norfloxacin, omeprazole, paclitaxel, phenytoin, piroxicam, quinapril, ramipril, risperidone, sertraline, simvastatin, terbinafine, terfenadine, triamcinolone, valproic acid, zolpidem, and pharmaceutically acceptable salts thereof.

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40. (New) The composition of claim 1, wherein the drug is selected from the group consisting of naproxen, glipizide, and nifedipine

41. (New) The dosage form of claim 14, wherein the surface stabilizer is selected from the group consisting of gelatin, casein, lecithin, dextran, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, poloxamers, poloxamines, Tetronic 1508[®], dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a mixture of sucrose stearate and sucrose distearate, p-isonylphenoxypoly-(glycidol), Crodestas SL-40[®], SA9OHCO, decanoyl-N-methylglucamide, n-decyl β-D-glucopyranoside, n-decyl β-D-maltopyranoside, n-dodecyl β-D-glucopyranoside, n-dodecyl β-D-maltoside, heptanoyl-N-methylglucamide, n-heptyl-β-D-glucopyranoside, n-heptyl β-D-thioglucoside, n-hexyl β-D-glucopyranoside, nonanoyl-N-

methylglucamide, n-noyl β -D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl- β -D-glucopyranoside, and octyl β -D-thioglucopyranoside.

42. (New) The dosage form of claim 14, wherein the drug is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antiasthma agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antitussives, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, antipyretics, immunosuppressants, immunostimulants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, bronchodilators, cardiac inotropic agents, chemotherapeutics, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, proteins, polypeptides, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, hormones, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vaccines, vasodilators, and xanthines.

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43. (New) The dosage form of claim 14, wherein the drug is selected from the group consisting of alprazolam, amiodarone, amlodipine, astemizole, atenolol, azathioprine, azelatine, beclomethasone, budesonide, buprenorphine, butalbital, carbamazepine, carbidopa, cefotaxime, cephalexin, cholestyramine, ciprofloxacin, cisapride, cisplatin, clarithromycin, clonazepam, clozapine, cyclosporin, diazepam, diclofenac sodium, digoxin, dipyridamole, divalproex, dobutamine, doxazosin, enalapril, estradiol, etodolac, etoposide, famotidine, felodipine, fentanyl citrate, fexofenadine, finasteride, fluconazole, flunisolide, flurbiprofen, fluvoxamine, furosemide, glipizide, gliburide, ibuprofen, isosorbide dinitrate, isotretinoin, isradipine, itraconazole, ketoconazole, ketoprofen, lamotrigine, lansoprazole, loperamide, loratadine, lorazepam, lovastatin, medroxyprogesterone, mefenamic acid, methylprednisolone, midazolam, mometasone, nabumetone, naproxen, nicergoline, nifedipine, norfloxacin, omeprazole,

paclitaxel, phenytoin, piroxicam, quinapril, ramipril, risperidone, sertraline, simvastatin, terbinafine, terfenadine, triamcinolone, valproic acid, zolpidem, and pharmaceutically acceptable salts thereof.

44. (New) The dosage form of claim 14, wherein the drug is selected from the group consisting of naproxen, glipizide, and nifedipine.

45. (New) The method of claim 30, wherein the surface stabilizer is selected from the group consisting of gelatin, casein, lecithin, dextran, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, poloxamers, Tetronic 1508[®], dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a mixture of sucrose stearate and sucrose distearate, p-isobutylphenoxy poly-(glycidol), Crodestas SL-40[®], SA9OHCO, decanoyl-N-methylglucamide, n-decyl β-D-glucopyranoside, n-decyl β-D-maltopyranoside, n-dodecyl β-D-glucopyranoside, n-dodecyl β-D-maltoside, heptanoyl-N-methylglucamide, n-heptyl-β-D-glucopyranoside, n-heptyl β-D-thioglucoside, n-hexyl β-D-glucopyranoside, nonanoyl-N-methylglucamide, n-nonyl β-D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl-β-D-glucopyranoside, and octyl β-D-thioglucopyranoside.

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46. (New) The method of claim 30, wherein the drug is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic

agents, antiasthma agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antitussives, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, antipyretics, immunosuppressants, immunostimulants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, bronchodilators, cardiac inotropic agents, chemotherapeutics, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, proteins, polypeptides, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, hormones, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vaccines, vasodilators, and xanthines.

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47. (New) The method of claim 30, wherein the drug is selected from the group consisting of alprazolam, amiodarone, amlodipine, astemizole, atenolol, azathioprine, azelatine, beclomethasone, budesonide, buprenorphine, butalbital, carbamazepine, carbidopa, cefotaxime, cephalexin, cholestyramine, ciprofloxacin, cisapride, cisplatin, clarithromycin, clonazepam, clozapine, cyclosporin, diazepam, diclofenac sodium, digoxin, dipyridamole, divalproex, dobutamine, doxazosin, enalapril, estradiol, etodolac, etoposide, famotidine, felodipine, fentanyl citrate, fexofenadine, finasteride, fluconazole, flunisolide, flurbiprofen, fluvoxamine, furosemide, glipizide, gliburide, ibuprofen, isosorbide dinitrate, isotretinoin, isradipine, itraconazole, ketoconazole, ketoprofen, lamotrigine, lansoprazole, loperamide, loratadine, lorazepam, lovastatin, medroxyprogesterone, mefenamic acid, methylprednisolone, midazolam, mometasone, nabumetone, naproxen, nicergoline, nifedipine, norfloxacin, omeprazole, paclitaxel, phenytoin, piroxicam, quinapril, ramipril, risperidone, sertraline, simvastatin, terbinafine, terfenadine, triamcinolone, valproic acid, zolpidem, and pharmaceutically acceptable salts thereof.

48. (New) The method of claim 30, wherein the drug is selected from the group consisting of naproxen, glipizide, and nifedipine.

49. (New) The method of claim 35, wherein the surface stabilizer is selected from the group consisting of gelatin, casein, lecithin, dextran, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, poloxamers, poloxamines, Tetronic 1508[®], dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a mixture of sucrose stearate and sucrose distearate, p-isonylphenoxy poly-(glycidol), Crodestas SL-40[®], SA9OHCO, decanoyl-N-methylglucamide, n-decyl β-D-glucopyranoside, n-decyl β-D-maltopyranoside, n-dodecyl β-D-glucopyranoside, n-dodecyl β-D-maltoside, heptanoyl-N-methylglucamide, n-heptyl-β-D-glucopyranoside, n-heptyl β-D-thioglucoside, n-hexyl β-D-glucopyranoside, nonanoyl-N-methylglucamide, n-noyl β-D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl-β-D-glucopyranoside, and octyl β-D-thioglucopyranoside.

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50. (New) The method of claim 35, wherein the drug is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antiasthma agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antitussives, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, antipyretics, immunosuppressants, immunostimulants, antithyroid agents, antiviral agents, anxiolytic

sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, bronchodilators, cardiac inotropic agents, chemotherapeutics, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, proteins, polypeptides, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, hormones, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vaccines, vasodilators, and xanthines.

51. (New) The method of claim 35, wherein the drug is selected from the group consisting of alprazolam, amiodarone, amlodipine, astemizole, atenolol, azathioprine, azelatine, beclomethasone, budesonide, buprenorphine, butalbital, carbamazepine, carbidopa, cefotaxime, cephalexin, cholestyramine, ciprofloxacin, cisapride, cisplatin, clarithromycin, clonazepam, clozapine, cyclosporin, diazepam, diclofenac sodium, digoxin, dipyridamole, divalproex, dobutamine, doxazosin, enalapril, estradiol, etodolac, etoposide, famotidine, felodipine, fentanyl citrate, fexofenadine, finasteride, fluconazole, flunisolide, flurbiprofen, fluvoxamine, furosemide, glipizide, gliburide, ibuprofen, isosorbide dinitrate, isotretinoin, isradipine, itraconazole, ketoconazole, ketoprofen, lamotrigine, lansoprazole, loperamide, loratadine, lorazepam, lovastatin, medroxyprogesterone, mefenamic acid, methylprednisolone, midazolam, mometasone, nabumetone, naproxen, nicergoline, nifedipine, norfloxacin, omeprazole, paclitaxel, phenytoin, piroxicam, quinapril, ramipril, risperidone, sertraline, simvastatin, terbinafine, terfenadine, triamcinolone, valproic acid, zolpidem, and pharmaceutically acceptable salts thereof.

52. (New) The method of claim 35, wherein the drug is selected from the group consisting of naproxen, glipizide, and nifedipine.